PATENT
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In re Application of:	)	
	)	
Louis Michael CROWE et al.	)	Confirmation No.: 5507
	)	
Application No.: 10/047,383	)	Group Art Unit: 3762
	)	
Filed: January 14, 2002	)	Examiner: George Robert Evanisko
	)	
For: APPARATUS FOR STIMULATING A MUSCLE OF A SUBJECT	)	

Commissioner for Patents
Arlington, VA 22202

Sir:

SUBMISSION OF PRIORITY DOCUMENT

Under the provisions of 35 U.S.C. § 119, Applicant hereby claims the benefit of the filing date of Ireland Application No. S2001/0032, filed January 16, 2001 for the above-identified United States Patent Application.

In support of Applicant's claim for priority, filed herewith is one certified copy of the above.

Respectfully submitted,

DRINKER BIDDLE & REATH LLP

By: ______________________
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Dated: July 5, 2007

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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2001/0032
Date of Filing	16 January 2001
Applicant	BMR RESEARCH & DEVELOPMENT LIMITED, An Irish company of Parkmore Business Park West, Galway.

Dated this 30 day of May 2007.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S010032

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

[ ] the grant of a patent under Part II of the Act

[x] the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

BMR RESEARCH & DEVELOPMENT LIMITED

Address

Parkmore Business Park West, Galway.

Description/Nationality

An Irish company.

2. Title of Invention

"Apparatus for stimulating a muscle of a subject"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

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Both Irish citizens.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**

The applicant has derived the right to be granted a Patent from the inventors by virtue of a Deed of Assignment dated January 4, 2001.

6. **Items accompanying this request – tick as appropriate**

(i) [x] Prescribed filing fee (£ 50.00)

(ii) [ ] Specification containing a description and claims

[x] Specification containing a description only

[x] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: ....

Filing Date: ....

8. **Agent**

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	54 Merrion Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**

F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed Conor Minogue

BMR RESEARCH & DEVELOPMENT LIMITED

BY: CONOR MINOGUE

CAPACITY: Director

Date 5/1/2001

Oifig na bPaitinní

BAILEATHE

16 JAN 2001

"Apparatus for stimulating a muscle of a subject"

The present invention relates to apparatus for stimulating a muscle of a subject, and in particular, to such apparatus for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject. The invention also relates to a method for stimulating a muscle in a subject for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject.

According to the invention there is provided apparatus for stimulating a muscle of a subject for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject, the apparatus comprising a signal generator for generating an electrical pulse signal, and a means for applying the signal to nerves associated with the muscle to be stimulated or adjacent the muscle of the subject for stimulating the muscle, wherein the signal generator generates the pulse signal of frequency and current amplitude for inducing contractions in the muscle at a frequency in the range of 3Hz to 12Hz, and preferably, at a frequency of 4Hz to 8Hz. Advantageously, the frequency and current amplitude of the signal is such as to maximise the bulk of the muscle being subjected to the contractions.

In one embodiment of the invention the pulse signal generated by the signal generator is of frequency and current amplitude for minimising discomfort to the subject.

The pulse signal may comprise a plurality if single pulses at a frequency for inducing the contractions in the muscle of the subject within the frequency range of 3Hz to 12Hz, or may comprise a plurality of bursts of pulses, the frequency of the respective bursts of pulses being such as to induce contractions in the muscle of the subject within the frequency range of 3Hz to 12 Hz, and the current amplitude and frequency of the pulses within each burst of pulses being such as to avoid contractions of the muscle at frequencies above 12Hz.

Preferably, the current amplitude of the pulses of the pulse signal, and the means for applying the pulse signal to the subject co-operate with each other to avoid the current density exceeding 0.02 mA/mm^2 in the subject adjacent the means for applying the pulse signal to the subject.

In one embodiment of the invention the current density in the subject adjacent the means for applying the pulse signal to the subject does not exceed 0.1 $m/A/mm^2$.

In one embodiment of the invention the maximum current amplitude of the pulse signal does not exceed 200 mA and preferably, the current amplitude of the pulse signal lies in the range of 80mA to 200mA, and advantageously, in the range 100mA to 200mA.

In a further embodiment of the invention the means for applying the pulse signal to the subject comprises an electrode pad, and preferably, a pair of electrode pads, the effective electrically conductive contact area of each electrode pad which can be placed an electrical contact with the subject being not less than 7,500 mm^2, and

preferably, not less than 10,000 mm^2, and advantageously, is not less than 15,000 mm^2.

In one embodiment of the invention at least one of the electrode pads is of effective electrical contact area such that the length of the effective electrical contact area is substantially similar to the width of the muscle to be stimulated.

In an embodiment of the invention where it is desired to stimulate a quadriceps or hamstring muscle group in a male of average size, it is preferred that the length of the effect of electrical contact area of the relevant electrode pad should be at least 140 mm, and preferably, at least 190 mm.

In another embodiment of the invention when the pulse signal comprises a plurality of single pulses the frequency of the respective pulses lies in the range 3Hz to 12Hz, and preferably, in the range 4Hz to 8Hz. Advantageously, when the pulse signal comprises a plurality of bursts of pulses, the frequency of the bursts lie in the range of 3Hz to 12Hz, and preferably, in the range 4Hz to 8Hz. Preferably, the frequency of the pulses within each burst of pulses should be greater than 20 Hz. In one embodiment of the invention the current amplitude of the respective pulses within each burst are within an envelope which defines a curve which rises from a first lower current amplitude value to a peak current amplitude value, and then returns to a second lower amplitude value. In another embodiment of the invention the first and second lower current amplitude values are similar. In another embodiment of the invention two adjacent pulse signals of each burst of pulse signals adjacent to the peak amplitude value of the envelope are of similar current amplitude value.

In another embodiment of the invention, the respective first and second lower amplitude values do not exceed more than 50% of the peak amplitude value.

In another embodiment of the invention where each burst of pulses comprises two or more pulses, the respective pulses in the burst of pulses may be of similar or different current amplitude values.

Further the invention provides use of the apparatus according to the invention for stimulating a muscle of a subject for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject.

The invention also provides a method for stimulating a muscle of a subject for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject, the method comprising the steps of applying an electrical pulse signal to the nerve associated with the muscle to be stimulated or to the muscle, wherein the signal generator generates the pulse signal of frequency and current amplitude for inducing contractions in the muscle at a frequency in the range of 3Hz to 12Hz, and preferably, at a frequency of 4Hz to 8Hz. Advantageously, the frequency and current amplitude of the signal is such as to maximise the bulk of a muscle being subjected to the contractions.

In one embodiment of the invention the pulse signal generated by the signal generator is of frequency and current amplitude for minimising discomfort to the

subject.

While in the past it has generally been believed that muscle stimulation by electrical pulse signals was ineffective in inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage to bring about weight loss in the subject, it has been surprisingly found that the apparatus according to the present invention is particularly effective for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject. To facilitate an understanding of the invention a non-limiting example of apparatus according to the invention will be described, and examples of use of the invention in inducing cardiovascular training effects in a subject, and in inducing relatively significant calorie usage to bring about weight loss in the subject will then be described. The apparatus is described with reference to the accompanying drawings in which:

Fig. 1 is a block diagram of apparatus according to the invention for stimulating a muscle of a subject for inducing cardiovascular training effects in a subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject,

Figs 2(a) to (c) are graphical representations of pulse signals which may be produced by the apparatus,

Figs. 3(a) and (b) are diagrammatic representations of use of the apparatus of Fig. 1,

Figs. 4(a) and (b) are diagrammatic representations, also of use of the apparatus of Fig. 1, and

Figs. 5(a) and (b) are graphical representations of parameters of a subject undergoing a trial with the apparatus of Fig. 1.

Referring to the drawings there is illustrated apparatus according to the invention indicated generally by the reference numeral 1 for stimulating muscles of a subject for inducing cardiovascular training effects in the subject, and for inducing relatively significant calorie usage which may bring about weight loss in the subject. The apparatus 1 comprises a signal generator 2 for generating a square wave electrical pulse signal for applying to a subject through two or more electrode pads for stimulating one or more muscles of the subject. In this particular case two sets of four electrode pads 4a, 4b, 4c and 4d are provided, one set for each leg, for stimulating the hamstring, the quadriceps, the glutei and calf muscle groups. A switching circuit 5 permits the pulse signals from the signal generator 2 to be selectively applied to the electrode pads 4.

The signal generator 2 is a variable frequency and variable current amplitude generator and is suitable for generating pulse signals at selectable frequencies, and of selectable constant current amplitudes as well as selectable varying current amplitudes. Typically, the signal generator 2 is capable of generating trains of pulse signals of frequency up to 200Hz and current amplitude up to 200 mA. Referring to Figs. 2(a) to (c) typical pulse trains which may be generated by the signal generator 2 are illustrated. Fig. 2(a) illustrates the simplest form of pulse signal where the

current amplitude is maintained constant at a selected value, and the frequency is also maintained constant. It has been found when this pulse train is selected the ideal frequency should lie in the range of 4Hz to 8Hz, and the current amplitude should lie in the range 100 mA to 200 mA. By selecting the frequency of the pulses to be in the range of 4Hz to 8Hz, the frequency of contractions induced in the selected muscles is similar to the pulse frequency. The current amplitude is selected to avoid discomfort to the subject. Fig. 2(b) illustrates a pulse signal comprising bursts of pulse signals, each burst comprising two signals of differing selectable constant current amplitudes. The frequency of the bursts and the frequency of the pulse signals in each burst are selectable and variable. When this train of pulse signals is used the frequency of the bursts should preferably lie in the range of 4Hz to 8Hz while the frequency of the pulses within each burst should be greater than 20Hz. The current amplitude of the first pulse A in each burst should lie in the range of 50% of the second pulse of each burst, and the second pulse B of each burst should be of current amplitude in the range of 100 mA to 200 mA.

The pulse train illustrated in Fig. 2(c) is of selectable constant frequency and selectable varying constant current amplitude. The pulse train comprises a plurality of bursts of pulse signals, the frequency of each burst of pulse signals being in the range of 4Hz to 8Hz. Each burst of pulse signals comprises six pulses which form an envelope commencing with a first lower current amplitude pulse raising to two adjacent similar peak current amplitude pulses B and then falling to a lower second current amplitude pulse A. The first and second lower current amplitude pulses A are of similar current which is in 50% of the current amplitude of the peak pulses B.

The current amplitude of the two adjacent peak pulses B is in the range of 100 mA to 200 mA. The frequency of the pulses within each burst of pulses is constant and greater than 20 Hz, and may be as high as 200Hz..

It is important that the frequency of the pulses within each burst should be of frequency at least 20 Hz, otherwise, each pulse within the bursts of pulses could stimulate a muscle contraction.

The effective electrical contact area of each electrode pad 4 which is contactable with the skin of the subject should be such as to ensure that the current density in the subject adjacent to the electrode pad does not exceed 0.02 mA per mm^2 for a maximum current amplitude of 200 mA. Thus, in order to achieve this it is necessary to determine the area of the electrode pads in conjunction with the maximum current amplitude of the pulse train to be applied to the subject. Ideally with a pulse train of maximum current amplitude of 200 mA, the electrode pads 4 should have an effective electrical contact area preferably of the order of 10,000 mm^2 or greater. Ideally, the pads 4 should be rectangular of dimensions 200 mm by 100 mm.

Referring now in particular to Figs. 3 and 4, the electrodes 4 are placed on the respective muscle groups. In this case, the electrode pads 4a are placed on the hamstring muscle groups of the respective legs, the electrode pads 4b are placed on the quadriceps muscle groups, the electrode pads 4c are placed on the glutei muscle groups, while the electrode pads 4d are placed on the calf muscle groups of the respective legs. Pulses with any of the selected parameters described above are applied to the subject through the electrode pads 4a to 4d. The direction in

which the current is applied through the electrode pads 4 to the subject is selectable through the switching circuit 5. One method for applying the pulse signals to the subject is to select the electrode pads 4 in pairs whereby one pair comprises the electrode pads 4a on the respective legs of the subject, and the other pairs comprise the electrode pads 4b, 4c, and 4d on the respective legs of the subject. The pulse signal is thus applied to the respective hamstring muscle groups through the electrode pads 4a, the pulse signal is applied to the quadriceps muscle groups through the electrode pads 4b while the pulse signal is applied to the glutei muscle groups through the pads 4c and similarly the electrode pulses are applied to the calf muscle groups through the pads 4d. The pulse signals for the respective muscle groups may be the same or different.

An alternative method for applying the pulse signals to the subject is to select the electrode pads on each leg so that the pulse signal is applied through the glutei and calf muscle groups on each leg through the corresponding glutei and calf electrode pads 4c and 4d, while the pulse signal is applied to the hamstring and quadriceps muscle groups on each leg through the hamstring pad 4a and the quadriceps pad 4b on the corresponding leg. Again, the parameters of the respective pulse signals applied to the respective pairs of pads may be the same or different.

A further alternative method for applying the pulse signal to the subject is to place the hamstring pad 4a on the femur of each leg relative to the quadriceps pad and the glutei pad 4b and 4c so that current passing through the subject from the hamstring pad 4a passes in the directions of the arrows A of Fig. 3(a) and passes out of the subject through the quadriceps and the glutei pads 4b and 4c, respectively. The

electrode pads 4a, 4b and 4c can then be arranged so that the current passes through the nerves which activate the hamstring, quadriceps and glutei muscles for in turn stimulating these muscles in the respective legs. This arrangement and selection of electrode pads allows for the stimulation of the calf muscle of each leg without the need for placing electrode pads specifically on the calf muscles of the respective legs.

It has been found that in order to induce a relatively significant calorie usage which may bring about weight loss in the subject, the energy usage by stimulating the muscles must be of sufficient intensity that it brings about a cardiovascular training effect in the subject. In general, it has been found that the energy usage should be at least and preferably above 50% of the maximum cardiac output. It has been found that this can best be achieved by ensuring that the maximum muscle bulk possible is stimulated and that it is stimulated at the optimal rate, while at the same time avoiding discomfort to the subject. It is known that the body is capable of generating internal heat by shivering. Shivering is caused by rapid muscle contractions without gross movement of the limbs. In general, it would be assumed that the greater the rate of muscle contracts during shivering, the greater would be the amount of heat generated. However, it has been found that this is not the case and that muscle contractions during shivering remain relatively constant between 4Hz to 8Hz irrespective of the temperature of the body. However, in order to increase the heat generating capacity of the muscles during shivering the muscle bulk which is subjected to shivering is increased. It has further been found that for a given muscle it appears that there is an optimal rate of contraction and relaxation that produces the optimal amount of energy with little or no external work. This rate

lies within the frequency range of 4Hz to 8Hz. Secondly, within an individual muscle the contractions are almost synchronous, in other words contracting in parallel using energy but producing little internal work.

Accordingly, in view of the fact that muscles contract at a rate of between 4Hz and 8Hz during shivering, it has been found that by stimulating the muscles at this rate similarly causes maximum energy usage by the muscles, thus, leading to the burning of calories, and thus weight loss. It has been found that causing the muscles to contract at a rate below 3Hz or above 12Hz results in energy utilisation by the muscles diminishing rapidly. Thus, in order to cause the muscles to contract at a frequency in the range of 4Hz to 8Hz the pulse train should be selected to produce a single pulse or a burst of pulses at a frequency of 4Hz to 8Hz. While a single pulse at a frequency of 4Hz has been found to provide good stimulation of the muscles at the desired 4Hz to 8Hz contraction rate, it has been found that bursts of pulses at 4Hz to 8Hz where each burst comprises two pulses provide a significantly increased energy utilisation by the muscles. The ideal pulse train is that illustrated in Fig. 2(b) whereby each burst comprises two pulses at a frequency of 25Hz whereby the first pulse is of current amplitude approximately half that of the current amplitude of the second pulse, and the amplitude of the second pulse is in the range of 100 mA to 200n mA. The frequency of the bursts is between 4Hz and 8Hz as desired. While the provision of a third pulse in each pulse burst would further increase energy usage by the muscles, the stimulation becomes less comfortable for the subject since the contractions begin to become titanic. This, thus, prevents the subject increasing the amplitude of the signal, and in turn the current density in the subject adjacent to the electrode pads in order to increase the muscle bulk which is being

stimulated.

As discussed above it is important to maximise the muscle bulk which is being stimulated, and this is achieved by maximising the current amplitude of the signal. Additionally, by ensuring relatively large effective electrical contact area of the electrode pads the higher current amplitude signals may be tolerated, without increasing the current density in the subject adjacent to the electrode pads.

By using the pulse train illustrated in Fig. 2(b) it has been found that the first pulse of lower amplitude of each burst causes some of the targeted muscles to be stimulated, while the second pulse of higher amplitude causes the remainder of the targeted muscles to be stimulated. However, the second pulse in each burst does not induce an additional contraction in the muscles which have commenced contraction as a result of the first of the two pulses, rather, the second pulse merely continues the contraction commenced by the first pulse. This is due to the fact that the frequency of the pulses of each burst is of frequency not less than 20 Hz. By providing the first pulse in each burst as being the lower amplitude pulse significantly less discomfort is caused to the subject for a given value of current amplitudes for the two pulses.

The pulse train of Fig. 2(c) has also been found to be effective, and minimises discomfort to the subject. However, it is important that the frequency of the pulses within each burst should not fall below 20Hz, otherwise, they would tend to act as individual pulses, and thus, each pulse would cause a contraction which would thus cause the muscles to contract at the frequency of the pulses in the pulse signal.

It has further been found that to maximise energy usage and thus weight lost, the muscles targeted for stimulation are important, as is the position at which the electrode pads are placed on the subject, and as discussed above the effective electrical contact area of the electrode pads. In order to achieve energy usage by the muscles to achieve reasonable weight loss, it is desirable that the large muscles of the legs should be stimulated. The muscles of the thorax and arms may also be stimulating thus adding to the total energy usage, and in turn the amount of calories burnt off. As discussed above it is desirable that the effective electrical contact area of the electrode pads should be at least 7,500 mm^2. However, the effective electrical contact area will depend on the size of the subject, bigger subject requiring larger electrical contact area pads, and the muscle groups to be stimulated, as well as the positioning of the electrode pads. If, for example, the pulse signals are being sent from one muscle group in one leg to a similar muscle group in the other leg of the subject, the effective electrical contact area of the electrode pads may be solely determined by the requirement of each muscle group independently. In this case a large person would typically require electrode pads of effective electrical contact area of 200mm X 100mm, electrode pads of this size should be sufficient for all muscle groups. On the other hand, a smaller person may require smaller pads, particularly, for the glutei muscle and muscles of the calf. In certain cases, it may be undesirable to pass the pulse signals from one leg to the other through the pelvis as this may lead to unacceptable discomfort to the subject.

It has also been found that in order to improve the level of comfort of the subject, as well as for convenience and electrical efficiency, the calf muscles of the leg of the subject should not be stimulated by placing electrode pads directly over the calf

muscle group, but rather by passing the pulse signals through the sciatic nerve above the knee. This can be achieved by passing pulse signals from the hamstring electrode 4a to the quadriceps electrode 4b and the glutei electrode 4c simultaneously as illustrated by the arrows A in Fig. 3(a). In order to ensure maximum quadriceps and hamstring contractions a separate pulse may be sent from the hamstring electrode 4a to the quadriceps electrode 4b without any pulse signal being transmitted or received by the glutei electrode 4c. This latter pulse may be sent relatively close in time to the other pulse, for example, after an interval of less than 15 milliseconds so that the perceived frequency of the muscle contraction is unchanged.

It is desirable that the quadriceps electrode 4b should be placed high and centrally on the leg so that it covers at least in part the femoral triangle of the femoral nerve underneath. The quadriceps electrode 4b may be inclined so that it runs below the inguinal crease at the top of the leg. The hamstring electrode pad 4a should be placed centrally and in the upper half of the hamstring muscle. The glutei electrode pad 4c should be placed centrally and over the bulk of the glutei muscle.

Ideally, the electrode pads are supplied in a garment or on bands or belts for facilitating easy and accurate placement on the subject.

It has been found that by using relatively large electrode pads as discussed above, and furthermore, by providing the pulse signals to the subject as discussed above currents of up to 200 mA can be tolerated by a subject, where heretofore the maximum tolerable current was approximately 30 mA.

The following examples demonstrate the effectiveness of the apparatus 1 according to the invention in achieving for inducing cardiovascular training effects in a subject, and for relatively significant calorie usage which may bring about weight loss in the subject.

Examples

A trial was carried out on nine subjects, namely, subjects aa, bb, ee, ff, hh, jj, kk, pp and rr. Results from these tests are set out in Tables 1 to 3. In the trial the apparatus 1 described with reference to Figs. 1 to 4 was used. Each subject was subjected to an average of twenty two sessions of muscle stimulation, and each session lasted for a time period of approximately one hour. In general, the pulse signals were applied to the subjects through eight electrode pads in two sets of electrode pads 4a to 4d as described with reference to Fig. 4, although, in some of the sessions, and in particular, towards the end of the trials the calf electrode pads 4d were dispensed with, as illustrated in Fig. 3. The hamstring, the glutei and the calf electrode pads 4a, 4c and 4d were placed horizontally over the corresponding hamstring, glutei and calf muscle groups, and the quadriceps pads 4b were placed over the quadriceps muscle groups adjacent the inguinal crease at a similar angle to the inguinal crease. The effective electrical contact area of the electrode pads was relatively large, and in each case the effective electrical contact area of the electrode pads was 20,000mm^2, the effect of electrical contact are being of dimensions 200mm by 100mm. In the sessions where the calf muscle electrodes 4d were dispensed with the electrode pads on each leg were selected so that the current applied to the hamstring electrode pads 4a passed through the subject and returned

through both the quadriceps pads 4b and the glutei pads 4c as illustrated by the arrows A in Fig. 3. Otherwise, the electrode pads were selected in pairs and the pulse signals were applied to the electrode pads 4 so that the pulse signals passed through the subject from each of the hamstring pad 4a, the quadriceps pad 4b, the glutei pad 4c and the calf pad 4d on one leg of the subject to the corresponding one of the hamstring pads 4a, the quadriceps pads 4b, the glutei pads 4c and the calf pads 4d on the other leg of the subject.

The pulse signal selected throughout the trials was the pulse signal illustrated in Fig. 2(b). The time period between the adjacent current amplitude pulses A and B of the pulse signal was one thirtieth of a second, while the bursts of the respective pulses A and B repeated every one fifth of a second. Thus, the frequency of the bursts of pulses was 5Hz while the frequency of the pulses was 30 Hz. The current amplitude of the first of the two pulses A and B was half the amplitude of the second pulse, while the amplitude of the second pulse was set in the case of each subject to be as high as the subject could comfortably tolerate, and in all cases was between 80 mA and 200 mA.

Referring now to Table 1 the level of fitness of each subject was determined prior to each subject commencing the trial and at the end of the trial. The fitness level was determined using the Queens College Step Test as described by W.D. McArdle, et al in "Exercise Physiology" fourth edition; by McArdle, Katch and Katch; published by Williams and Wilkins; at page 210. Based on the level of fitness determined by the Queens College Step Test a value of the maximum VO_2 for each subject was predicted prior to commencement of the trial. The predicted maximum VO_2 value for the subjects aa to rr is set out in the second column of Table 1. The third column of

table 1 sets out the maximum VO_2 value predicted for each subject at the end of the trial. Columns 4 and 5 of Table 1 set forth the percentage ranking of the subjects before and after the trials, respectively, again based on the Queens College Step Test. The percentage ranking is a way of expressing an individual's fitness in relation to a typical population of 100 Queen's College Students of the same sex as the individual. A percentage ranking of 80 would mean that the individual was fitter than 80% of the students (same sex). Another way to express the percentage ranking is to say that they are in the top 20% of students measured for their fitness levels. The "pre" and "post" columns refer to the measured fitness levels before and after the trials (respectively) with the muscle stimulation method described above.

Table 2 at Column 2 shows the VO_2 consumption of each subject before being subjected to the trial in ml per minute. Column 3 shows the VO_2 consumption of each subject per weight of the subject in kilograms also before commencing the trial. Column 4 in Table 2 shows the energy per minute in kilocalories per minute which could be expended by each subject prior to commencement of the trial. Table 3 shows corresponding results in the corresponding columns for each of the subjects after the trials were completed.

Graphs 1 and 2 in Figs. 4a and 4b illustrate the energy consumption and heart rate response of one of the subjects during a three hour period while under going one of the sessions of the trial. During this session the electrode pads 4d were dispensed with, and the pulse signals were applied to the subject through the electrode pads 4a, 4ba nd 4c as described above at Page 15, Line 16 to Page 16, Line 2. The pulse signals applied to the subject were as described above at Page 16, Line 9 to Line 17 with reference to Fig. 2(b). The subject was sitting with his legs supported.

There was no additional voluntary exercise. As is evident from Graph 1 the subject was exercising at a level greater than 600kcal/hr. This is the equivalent of jogging. From Graph 2 it can be seen that the heart rate of the subject during the session was, in general, in excess of 120 bpm, and this rapid heart rate would be expected to bring about significant training effects on the cardiovascular system.

From the results set forth in Tables 1 to 3 and Graphs 1 and 2 it can be seen that as well as inducing significant cardiovascular training effects in each of the subjects over the twenty two sessions of the trial, significant energy was expended by the subjects, which thus, would lead to significant weight loss. Further trials are being carried out to establish precise weight loss which can be achieved by using the apparatus as described.

It is envisaged that a number of safety features will be required in the apparatus in order to prevent excessive muscle stimulation, and in particular for avoiding overstressing of the subject. Due to the fact that the apparatus exercises the cardiovascular system it has the potential to overstrain the system, which could have serious and indeed fatal results on subjects with heart disease or other ailments. Accordingly, to overcome this problem a heart rate monitor may be provided from monitoring the heart rate of the subject, and the signal generator would be responsive to the heart rate monitor. It is also envisaged that a microprocessor will be provided which will allow the apparatus to be programmed so that the maximum allowable heart rate can be set depending on the subject, his or her heart condition, age and other relevant perimeters. The microprocessor would read signals from the heart rate monitor, and in turn would control the signal generator in response to the

signals read from the heart rate monitor.

Additionally, it is envisaged that the microprocessor could be programmed to control the length of each session, and the frequency with which a subject could subject his or herself to a session.

Other monitors as well as a heart rate monitor may be provided, for example, a BP monitor, a pulse oximeter, a glucose monitor, a respiratory monitor, an EMG monitor.. The heart rate monitor may be provided as an ECG monitor or any other suitable monitor. It is also envisaged that the apparatus may be responsive to changes in the ECG pattern, for example, ST segment depression or arrhythmias.

Indeed, in the case of the monitor being provided by an ECG or an EMG, in certain cases, it is envisaged that the electrode pads which are used for stimulating the muscles may also be used for picking up the ECG or EMG signals.

The monitor or monitors may be a discrete unit which could be hardwired to the apparatus, or may communicate with the apparatus through IRDA radio frequency, using blue tooth technology or the like.

It has also been found that fatigued muscles give a different EMG signal to non-fatigued muscles. This is true both in response to a pulse train which comprises single pulses at the appropriate 4Hz to 8Hz or bursts of pulses at higher frequencies whereby the frequency of the bursts is in the order of 4Hz to 8Hz, as well as in the recovery/relaxation phases of the stimulation session. Thus, the microprocessor

may be programmed in order to reduce the amplitude or amplitudes of the pulse signal or terminate a treatment session in the event of the EMG response showing signs of muscle fatigue. By way of example, if the magnitude of the EMG response to a given test signal sent out on a regular basis dips below, for example, 70% of the original response the unit may automatically reduce the amplitude or amplitudes of the pulse signal.

Those with peripheral vascular disease may not experience the normal warning signs during use of the apparatus, and accordingly, a pulse oximeter placed, for example, on a toe may be provided for terminating a treatment session if the oxygen haemoglobin saturation falls below, for example, 90%. Similar comments would apply should the monitoring means include a blood flow meter or a glucometer.

It is also envisaged that pulse signals may be sent from one of the electrode pads to another or to a set of electrode pads for determining the bioimpedence of the body. As the electrodes position while using the system will remain substantially constant during each session by monitoring the body impedence the subject may track his or her individual progress, thereby motivating the subject to persist.

Additionally, it is envisaged that a monitoring means for determining if a subject collapses during a session may be provided. In which case the microprocessor would immediately switch off the apparatus. Such a monitoring means may, for example, be provided by a tilt switch which would be placed on the subject which would trip out on the subject collapsing. In this particular case it is envisaged that the microprocessor may be programmed that on receiving such a signal would

communicate with the outside world for summoning assistance for the subject. Such communication may be through a telecommunications network, a radio transmission, or indeed by an alarm which would summon assistance from an adjacent room or the like.

Additionally, it is envisaged that the microprocessor may be programmed to personalise the apparatus to the needs of one or more subjects which will be using the apparatus, and monitor and store results of each treatment session so that the progress of each subject can be monitored.

It has also been found that the apparatus according to the invention as well as being suitable for facilitating weight loss and for increasing exercise tolerance of the subject, the apparatus may also be used in the treatment of many medical conditions, where vigorous exercise of large muscle groups would be beneficial.

Additionally, it has been surprisingly found that subjects are able to sleep quite comfortably with this type of muscle stimulation if it is used at submaximal levels. This method allows the muscles to contract very comfortably and thus not interfere with sleep when used at submaximal levels. In one embodiment of the invention the apparatus is programmed not to give any palpable pulses for a defined period of time, say two hours. This phase may also be terminated by changes in the heart rate or EEG that signify deep sleep. This allows the subject to fall asleep as usual. During the next phase after sleep has commenced the intensity of the pulses gradually increases over a period of time, for example, ten minutes. This avoids a sudden change that may awaken the subject. During the next phase the apparatus

is operated at a predetermined current amplitude level, in the range of 20% of maximal. This phase may last until the subject wakes up. Or it may last for a predetermined time, say four hours. In one embodiment of the invention the apparatus incorporates an alarm clock. The prolonged usage periods allow for significant amounts of energy to be expended during the night.

In one embodiment of the invention this nocturnal stimulation is linked to a heating or cooling device. To fall into a deep sleep an individual needs to be warm. However, if too much bed clothing is used a subject may be uncomfortably warm during the stimulation as heat is generated. To overcome this problem the apparatus functions in conjunction with an electric heater/blanket and/or a fan. During the periods when the energy consumption is low the electric blanket is on or at a higher level. Conversely when the energy consumption is high a fan or other cooling device works at a higher level.

$\boxed{\text{Table 1}}$

Subject	**Pre predicted VO_2 max**	**Post predicted VO_2 max**	**Pre % rank**	**Post % rank**
aa	34	38.5	30	90
bb	57.6	60.9	90	100
ee	60.9	60.9	100	100
ff	45.8	44.1	50	45
hh	36.3	37.7	70	85
jj	36.3	37	70	80
kk	29.6	34.8	5	45
pp	40.8	42.5	25	35
rr	45.8	50.9	50	75
mean	**43.0**	**45.3**	**54.4**	**72.8**
stdev	10.6	10.1	31.2	24.9

p = 0.24090001 significant **p = 0.0275936 significant**

Table 2

Subject	VO_2 (ml/min)	VO_2/kg	Kcal/min
aa	1019	18.54	5.1
bb	743	8.1	3.7
ee	869	13.8	4.3
ff	902	10.4	4.5
hh	594	8.25	2.84
jj	705	11.3	3.45
kk	997	17.5	4.9
pp	1225	11	6.1
rr	1207	16.5	6.04
mean	**917.9**	**12.8**	**4.5**
stdev	**217.3**	**3.9**	**1.1**
range	**594 - 1225**	**8.1 – 18.5**	**2.8 – 6.0**

Table 3

Subject	VO_2 (ml/min)	VO_2/kg	Kcal/min
aa	1363	24.8	6.7
bb	2484	27.7	12.3
ee	1861	29.5	9.25
ff	1814	20.9	9.03
hh	1243	17.26	6.03
jj	859	13.7	4.3
kk	1268	22.2	6.2
pp	2448	22.45	12.1
rr	1923	26.6	9.7
mean	**1659.9**	**22.8**	**8.4**
stdev	**556.7**	**5.1**	**2.8**
	859 - 2484	**13.7 – 29.5**	**4.3 – 12.3**

The invention is not limited to the embodiment hereinbefore described which may be varied in construction and detail.

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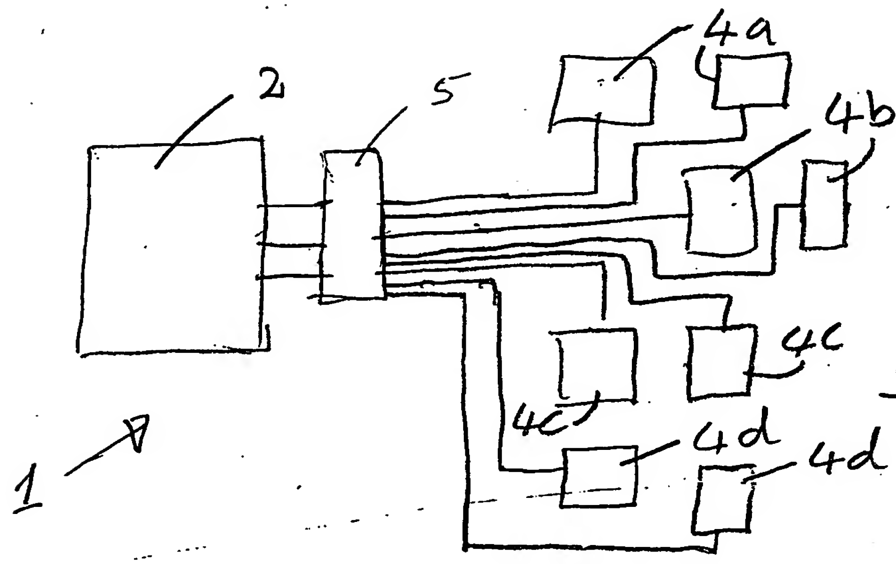
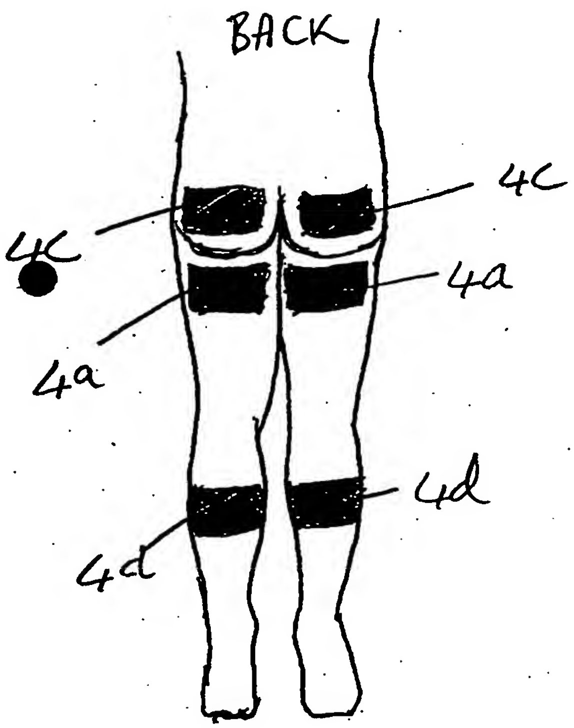
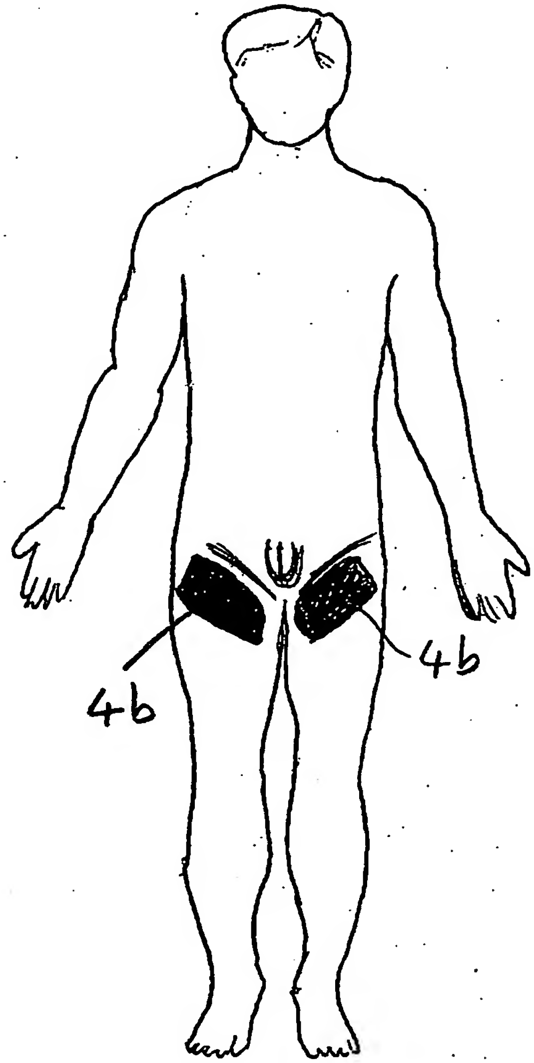


FIG 1



(a)



(b)

FIG 4

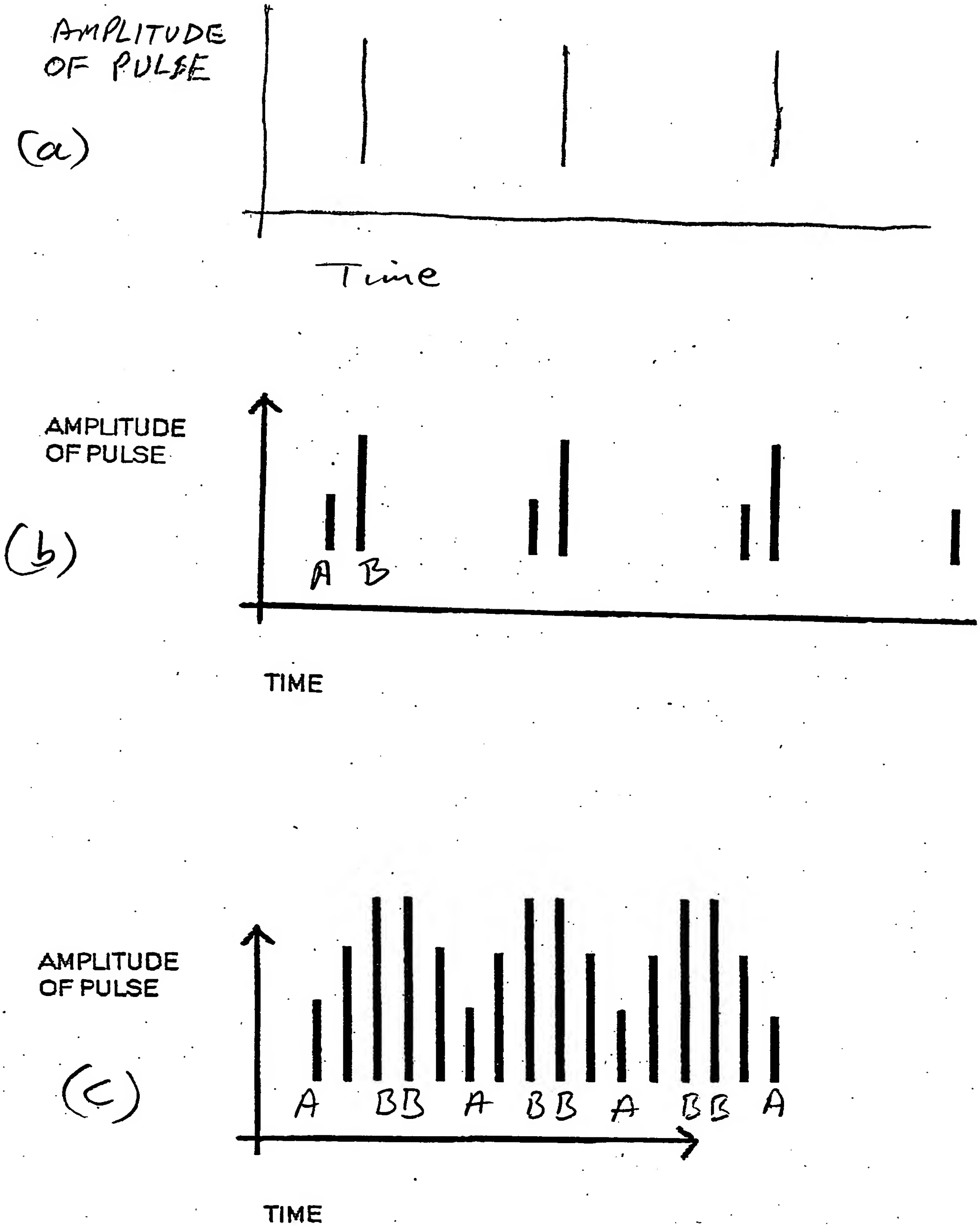
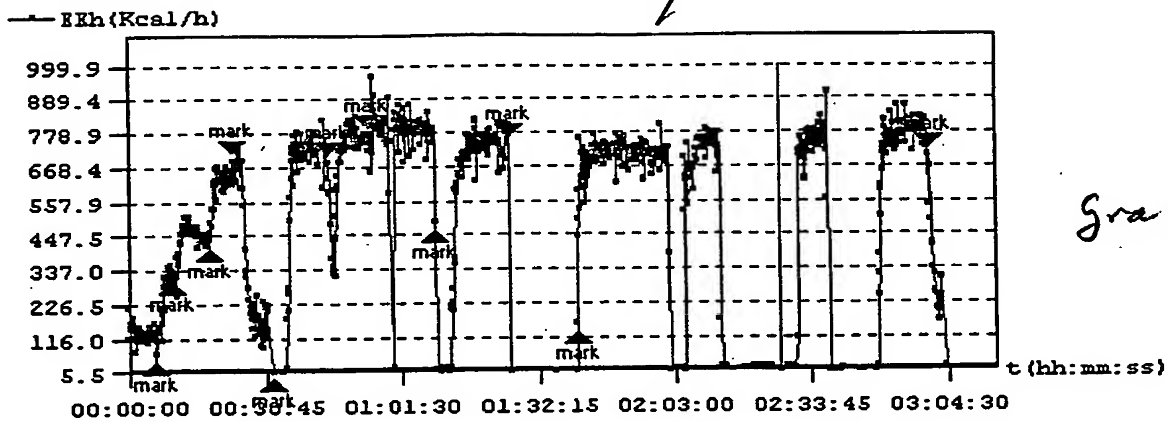
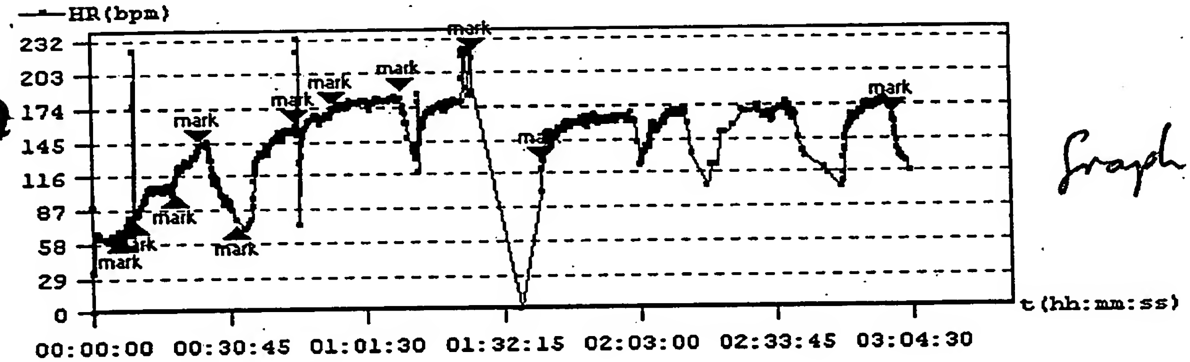

AMPLITUDE OF PULSE
(a)
Time
AMPLITUDE OF PULSE
(b)
A B
TIME
AMPLITUDE OF PULSE
(c)
A BB A BB A BB A
TIME

FIG 2

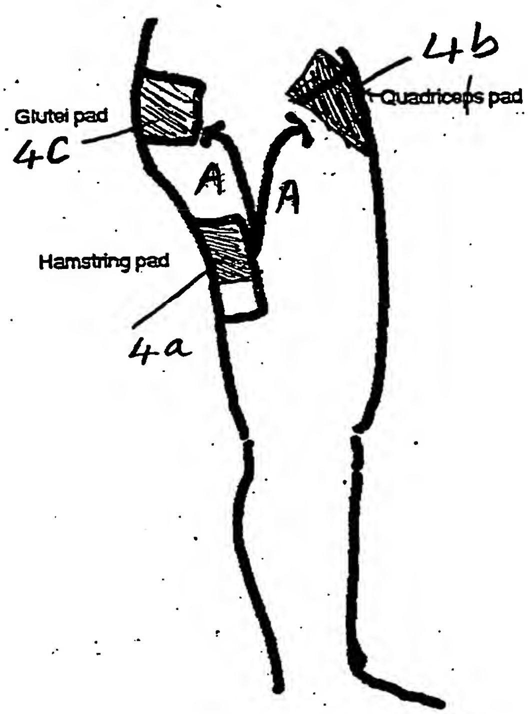


Graph 1 (a)

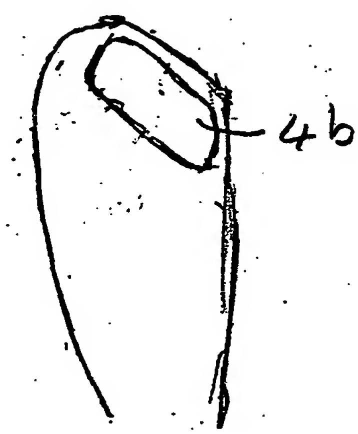


Graph 2 (b)

FIG 5



(a)



(b)

FIG 3